

## REMARKS

Claims 1-19 and 23-27 were pending in the above-captioned patent application prior to this amendment. Claims 20-22 were previously canceled. Claims 1, 2, 5, 12, and 13 are amended and new claims 28 and 29 are added herein. No new matter is believed to be entered by these amendments and new claims. Claims 8, 17, 18, and 26 are canceled herein.

### CLAIM REJECTIONS UNDER 35 U.S.C. § 102

The Examiner rejected claims 1-8, 12, 13, 16-19, 23, and 26 as being unpatentable under 35 U.S.C. §102(b). The Examiner relied upon Henley et al. WO 01/37922 A2 (hereinafter Henley) to support this rejection.

In the Examiner's rejection, the Examiner asserted that "Henley teaches a vacuum bandage system (6) capable of being used with a wound (300) having a wound surface, the vacuum bandage system (6) comprising: a wound dressing member (602, 618) having a plurality of holes (interstices in porous packing (618)) and a port (602, 620) in communication with the holes and capable of being coupled to a vacuum source (11), and a wound insert (604) capable of being placed within the wound (300) between the wound surface and the wound dressing member (602, 618), the insert (604) being made of a material which is not porous or foam-like (silicone) (see fig. 9, *infra*, from US equivalent Risk et al. US 6,755,807 B2.)"

The Examiner further asserted that "[r]egarding claim 8, Henley, incorporating by reference the '352 application, teaches a dressing construction of a non-porous material (silicone) (see Lockwood et al., col. 4, lines 50-67)."

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). Thus, a reference does not anticipate a claim if the claim contains any limitation that is neither literally nor inherently present in that reference.

Claim 1 is amended to incorporate the limitation of claim 8 to recite that the "wound dressing member [is] made of a generally non-porous material." Henley does not

disclose or suggest a vacuum bandage system including both “a wound dressing member made of a generally non-porous material” and “a wound insert . . . being made of a material which is not porous or foam-like.” As noted by the Examiner, Henley discloses a *porous* packing 618 used with the bandage member 604. The Examiner further references U.S. Patent Application No. 09/725,352 (now Lockwood et al. U.S. Patent No. 6,685,681 (hereinafter Lockwood)) which Henley incorporates by reference in order to illustrate further examples of bandages 14 and 15 of Henley. Lockwood discloses a wound care bandage 10 including a thin, flexible wound dressing member 20 being made of a medical grade silicone as noted by the Examiner at col. 4, ll. 50-67 of Lockwood. However, Lockwood does not disclose or suggest any vacuum bandage system having a “wound insert” and certainly does not disclose any such vacuum bandage system having both a “wound insert . . . being made of a material which is not porous or foam-like” and a “wound dressing member” positioned above the wound insert and which is “non-porous.” As noted above, Lockwood only discloses the wound dressing member 20.

Furthermore, claim 1 is amended to recite that the wound dressing member is “configured to engage at least a portion of the wound surface of the wound.” Henley does not disclose or suggest a vacuum bandage having both a “wound dressing member . . . configured to engage at least a portion of the wound” and “wound insert configured for placement within the wound between the wound surface and the wound dressing member.”

For the foregoing reasons, Applicants respectfully submit that independent claim 1 is not anticipated by Henley because neither Henley nor Lockwood, which is incorporated by reference therein, includes all of the limitations of claim 1. Accordingly, withdrawal of the 35 U.S.C. §102(b) rejection of claim 1 based on Henley, as well as claims 2-7 and 23 depending either direly or indirectly from claim 1, is respectfully requested.

Claim 12 is amended herein to require that the thin, flexible member of the wound insert includes “a top surface, a bottom surface, and side surfaces” and that “the passageways comprise bores through the body extending from one side surface to another.” Henley does not disclose or suggest such an insert. The bandage member 604 of Henley includes upper channels

606, lower channels 608, and apertures 614, as shown in FIG. 9 of Henley. However, the bandage member 604 of Henley does not include any "bores through the body extending from one side surface to another." In other words, the channels 606, 608 of Henley do not form "bores through the body" as is now recited in amended claim 12. Rather, such channels 606, 608 are formed in the top and bottom surfaces of the bandage member 604 of Henley. Furthermore, Lockwood (noted above as being incorporated by reference into Henley) does not disclose or suggest any such bores. Lockwood discloses a wound dressing member 20 having channels 28, 30, 32, and 34 as well as through holes 36. However, the member 20 does not include any "bores through the body extending from one side surface to another" as is now recited in claim 12. Accordingly, claim 12 is not anticipated by Henley and withdrawal of the U.S.C. §102(b) rejection of claim 12 based on Henley is respectfully requested.

Claim 13 is amended herein to recite that the claimed wound insert, which is made of a generally non-porous, flexible material, is also "cylindrical in shape." Neither Henley nor Lockwood (incorporated by reference into Henley) disclose or suggest any wound insert having a body which is cylindrical in shape. Accordingly, Henley does not anticipate claim 13 and withdrawal of the U.S.C. §102(b) rejection of claim 13, as well as claims 16 and 19 depending either directly or indirectly from claim 13, is respectfully requested.

The limitation regarding the cylindrical shape of the body of the insert was originally recited in claim 9, rejected by the Examiner under 35 U.S.C. §103(a) as being unpatentable over Henley. In making this rejection, the Examiner stated that "Henley does not disclose expressly the claimed sizes and shapes of the absorbent insert. Mere changes in size or shape are not sufficient to patentably distinguish an invention over the prior art absent a showing of criticality." The Examiner further stated that "Henley incorporates by reference the '352 application which teaches a dressing insert (20) that can be cut to fit the size and shape of a wound (see Lockwood et al. figures 4 and 6; col. 5, lines 1-10). At the time of the invention, it would have been obvious for one of ordinary skill in the art to provide the wound insert of

Henley in any size or shape that corresponds to a wound to which it is to be applied.” See pages 6 and 7 of the 8/10/07 Office Action.

Applicants assert that the cylindrical shape of the claimed body is a significant change from the thin, rectangular members disclosed by Henley and Lockwood. In particular, a cylindrical shape represents a considerable departure in shape from these prior bandage member configurations. Furthermore, the cylindrical body of the wound insert of claim 13 is provided for use within a long, generally cylindrical wound tunnel, such as wound tunnel 14 of wound 12 shown in FIG. 2 of the present application. Accordingly, a cylindrically-shaped wound insert conforms to the size of the wound tunnel for placement within the wound tunnel. The use of an insert shaped to fit such wound tunnels was not contemplated by the prior art.

While Lockwood discloses a wound dressing member 20 which can be cut to fit the size and shape of a wound, Lockwood does not disclose or suggest that such a thin, flexible, wound dressing member 20 may be cut to form a cylindrical body for placement within wound tunnels. Lockwood does not discuss wound tunnels or the placement of wound inserts within wound tunnels in addition to the use of a wound dressing member coupled to a vacuum source. Henley and Lockwood only disclose the use of a generally flat, rectangular wound dressing member 20. Further, Lockwood discloses only that the thin, flexible rectangular member 20 may be cut to fit a generally planar wound surface having either an irregular surface area and/or a surface area smaller than that of the member 20 itself. See FIGS. 4 and 6 of Lockwood. Lockwood does not disclose or suggest cutting the member 20 to form a cylinder. Further, neither Lockwood nor Henley disclose or suggest the use of a wound insert having “a body made of a generally non-porous flexible material, wherein the body is cylindrical in shape” for use with a wound dressing member coupled to a vacuum source. Accordingly, claim 13 is not anticipated by Henley nor is it obvious in view of Henley. Withdrawal of the U.S.C. §102(b) rejection of claim 13, as well as claims 16 and 19 depending either directly or indirectly from claim 13, is respectfully requested. Further, withdrawal of the U.S.C. §103(a) rejection of claim 9 based on Henley is respectfully requested.

The Examiner rejected claims 1 and 27 as being unpatentable under 35 U.S.C. §102(b). The Examiner relied upon La Mere et al. U.S. Patent No. 2,338,339 (hereinafter La Mere) to support this rejection.

In the Examiner's rejection, the Examiner asserted that "La Mere teaches a vacuum bandage system (11, 12, 13) capable of being used with a wound having a wound surface, the vacuum bandage system (11, 12, 13) comprising: a wound dressing member (14, 16) having a plurality of holes (17, 26) and a port (15) in communication with the holes (26) and capable of being coupled to a vacuum source (11), and a wound insert (M) capable of being placed within the wound between the wound surface and the wound dressing member (14, 16), the insert (M) being made of a material which is not porous or foam-like (rubber) (see fig. 3, *infra* (col. 3, line 1))." See page 5 of the 8/10/07 Office Action.

Respectfully, Applicants disagree with the Examiner's interpretation of La Mere. For example, La Mere is directed toward a massaging vibrator including a cup-shaped housing 14 and a massage element M coupled to the housing 14. La Mere does not disclose any "vacuum bandage system for use with a wound having a wound surface" and particularly does not disclose any "wound insert configured for placement within the wound between the wound surface and the wound dressing member," as is recited in claim 1. La Mere does not even disclose a wound, let alone any component of a vacuum bandage system "for placement within the wound." La Mere is only disclosed for placement on a patient's external skin surface and not for placement *within* a wound.

Further, Claim 1 requires that the wound dressing member is "configured to engage at least a portion of the wound surface of the wound." As noted above, La Mere is not configured for use with a wound. In particular, the cup-shaped housing 14 and partition 16 of La Mere (which the Examiner asserts operate as the "wound dressing member" of claim 1) is not configured to engage the wound surface of any wound. Rather, only the massage element M is provided to engage the external surface of a user's skin.

For these reasons, La mere does not anticipate claim 1 of the present application. Accordingly, withdrawal of this rejection as it applies to claim 1 as well as claim 27 depending from claim 1, is respectfully requested.

#### CLAIM REJECTIONS UNDER 35 U.S.C. § 103

The Examiner rejected claims 9-11, 14, 15, 24, and 25 as being unpatentable under 35 U.S.C. §103(a). The Examiner relied upon Henley to support this rejection.

Each of claims 9-11, 14, 15, 24 and 25 depends either directly or indirectly from one of independent claims 1 and 13 and incorporates all of the limitations of such claims therein. As such, in view of the amendments made to claims 1 and 13 and the arguments set forth above, the rejection of dependent claims 9-11, 14, 15, 24, and 25 is now moot. Accordingly, withdrawal of this 35 U.S.C. §103(a) rejection as it applies to claims 9-11, 14, 15, 24, and 25 is respectfully requested.

#### FURTHER ACTION

In view of the foregoing remarks, the subject application is now deemed to be in condition for allowance, and such action is respectfully requested. If there are any questions or comments that would speed prosecution of this application, the Examiner is invited to call the undersigned at (317) 231-7216. It is respectfully requested that if necessary this paper be considered as a petition for an extension of time sufficient to effect a timely response and that any extension of time fees, as well as any other fees, be charged to the Account of Barnes & Thornburg, Deposit Account No. 10-0435 with reference to file 7175-71861.

Respectfully submitted,  
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